U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

May 29, 2020

TO: Members, Committee on Energy and Commerce

FROM: Committee Republican Staff

RE: Hearing entitled, "On the Front Line: How Governors are Battling the COVID-19 Pandemic."

The Subcommittee on Oversight and Investigations will hold a virtual hearing on Tuesday, June 2, 2020, at 11:30 a.m., entitled "On the Front Line: How Governors are Battling the COVID-19 Pandemic."

I. WITNESSES

- The Honorable Asa Hutchinson, Governor of Arkansas;
- The Honorable Jared Polis, Governor of Colorado; and
- The Honorable Gretchen Whitmer, Governor of Michigan.

II. BACKGROUND

a. History and Spread of COVID-19

Coronavirus (CoV) is a large family of viruses that causes illness ranging from the common cold to more severe diseases such as Middle East Respiratory (MERS-CoV), which was first identified in Saudi Arabia in 2012, and Severe Acute Respiratory Syndrome (SARS-CoV), which was first identified in the Guangdong province of southern China in 2002.[1] Coronaviruses are zoonotic, meaning they are transmitted between animals and people, and several known coronaviruses are circulating in animals that have not yet infected humans. For example, SARS-CoV was transmitted from civet cats to humans, and MERS-CoV was transmitted from dromedary camels to humans.[2] A novel coronavirus (nCoV), like the one that is currently being transmitted, is a new strain that has not been previously identified in humans. COVID-19 is the infectious disease caused by the most recently discovered coronavirus, SARS-CoV-2, which was

[1] World Health Organization, *Coronavirus* (last visited on Mar. 3, 2020), *available at* https://www.who.int/health-topics/coronavirus; World Health Organization, Middle East respiratory syndrome coronavirus (MERS-CoV) (Dec. 20, 2019), *available at* https://www.who.int/news-room/q-a-detail/middle-east-respiratory-syndrome-coronavirus-(mers-cov); World Health Organization, *International travel and health, SARS* (Severe Acute Respiratory Syndrome) (last visited Mar. 3, 2020), *available at* https://www.who.int/ith/diseases/sars/en/.
[2] World Health Organization, *Coronavirus* (last visited on Mar. 3, 2020), *available at* https://www.who.int/health-topics/coronavirus.

discovered as a result of the outbreak in Wuhan, China in December 2019.[3] Currently, the specific source of the COVID-19 outbreak is unknown.

Common signs of COVID-19 infection include respiratory symptoms, fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea.[4] The Center for Disease Control and Prevention's (CDC) website notes that this list does not include all possible symptoms and it will continue to update the list as they learn more about the virus. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. Anyone can have mild to severe symptoms, but older adults and people who have underlying medical conditions, such as heart or lung disease or diabetes, seem to be at higher risk for developing more serious complications. According to the CDC, symptoms may appear two to 14 days after exposure.[5]

While initial cases were reported in Wuhan, China and other countries starting in early December 2019, the first reported patient in the U.S. with confirmed COVID-19 was in Washington State on January 22, 2020.[6] On January 31, 2020, the U.S. Department of Health and Human Services (HHS) Secretary, Alex M. Azar II, declared a public health emergency for the U.S. to aid the nation's health care community in responding to COVID-19, and announced travel restrictions and quarantines for individuals traveling from China, beginning on February 2, 2020, via a Presidential Proclamation issued by President Trump.[7] Additional travel restrictions for other countries have been issued since. During the week of February 23, 2020, CDC reported community spread of the virus in California, Oregon, and Washington. On March 11, 2020, the World Health Organization (WHO) announced that COVID-19 can be characterized as a pandemic.[8] According to the WHO, this is the first pandemic caused by a coronavirus.

[3] World Health Organization, *Q&A on coronavirus* (COVID-19) (Feb. 23, 2020), *available at* https://www.who.int/news-room/q-a-detail/q-a-coronaviruses.
[4] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Symptoms* (last reviewed May 13, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.
[5] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Symptoms* (last reviewed Feb. 29, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/about/symptoms.html.
[6] Jennifer Harcourt, Azaibi Tamin, et. al., *Centers for Disease Control and Prevention, Emerging Infectious Diseases*, Vol. 26, Num. 6-June 2020, *Severe Acute Respiratory Syndrome Coronavirus 2 from Patient with Coronavirus Disease, United States* (May 18, 2020), *available at* https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article.
[7] Proclamation on Suspension of Entry as Immigrants and Nonimmigrants of Persons who Pose a Risk of Transmitting 2019 Novel Coronavirus (Jan. 31, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-suspension-entry-immigrants-nonimmigrants-persons-pose-risk-transmitting-2019-novel-coronavirus/.
[8] World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020* (Mar. 11, 2020), *available at* https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

As of May 29, 2020, there are 188 countries/regions with a total of 5,840,369 confirmed COVID-19 cases and 361,066 deaths.[9] Within the U.S. there are 55 U.S.-affiliated jurisdictions reporting cases of COVID-19, including all 50 states, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands.[10] While there are 55 jurisdictions reporting cases, different parts of the country are seeing different levels of COVID-19 activity. For example, of the U.S. jurisdictions reporting cases, there are 31 states who have reported more than 10,000 cases of COVID-19.[11] As of May 28, 2020, CDC reports that there are 1,698,523 cases and 100,446 deaths from COVID-19 in the U.S.[12] However, CDC does not know the exact number of COVID-19 illnesses, hospitalizations, and deaths because the virus "can cause mild illness, symptoms might not appear immediately, there are delays in reporting and testing, not everyone who is infected gets tested or seeks medical care, and there may be differences in how states and territories confirm numbers in their jurisdictions."[13]

b. Transmission of COVID-19

While we are still learning about how COVID-19 spreads, the virus is thought to spread mainly from person-to-person between people who are in close contact with one another (within six feet), through respiratory droplets produced when an infected person coughs, sneezes, or talks.[14] These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. In addition, COVID-19 may spread by people who are not showing symptoms, also known as someone who is asymptomatic or pre-symptomatic.[15] In addition to person-to-person spread, it may be possible to contract COVID-19 by touching a surface or object that has the virus on it and then touching your mouth, nose, and possibly eyes.[16] Further, while it appears the virus can spread from people to animals, at this time, the CDC believes that the risk of transmission from animals to people is low.[17] According to the CDC, the virus is spreading more efficiently than influenza, but not as efficiently as measles.[18]

There is currently no vaccine to prevent COVID-19, therefore, the best way to prevent illness is to avoid being exposed to the virus. In addition, CDC has issued detailed recommendations on how everyone can help protect themselves from COVID-19 by doing things

[9] Johns Hopkins University & Medicine, Coronavirus Resource Center, COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (last visited May 29, 2020), *available at* https://coronavirus.jhu.edu/map.html.
[10] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Cases in the US* (last updated May 29, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html#accordion-1-collapse-2.
[11] *Id*.
[12] *Id*.
[13] *Id*.
[14] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), How It Spreads* (last reviewed May 22, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fprepare%2Ftransmission.html.
[15] *Id*.
[16] *Id*.
[17] *Id*.
[18] *Id*.

such as wearing masks, thoroughly washing their hands, and avoiding close contact with people who are sick, among other things.[19]

III. TESTING FOR COVID-19

a. Types of Tests for COVID-19

There are currently two types of COVID-19 tests available—diagnostic tests, or viral detection tests, and antibody tests. Results from a diagnostic test indicate whether an individual has a current infection while results from an antibody test indicate whether an individual had a previous infection. As of May 27, 2020, the U.S. Food and Drug Administration (FDA) had worked with more than 400 tests developers and has authorized 113 tests under Emergency Use Authorizations (EUAs), which include 100 molecular tests, 12 antibody tests, and 1 antigen test.[20] Both molecular tests and antigen tests are diagnostic tests.[21]

As of May 28, 2020, 15,766,114 COVID-19 test results had been reported, and 1,897,701 of those were positive test results.[22] Some states have included both antibody tests and viral tests in their submissions to CDC on total test counts; CDC and states are rapidly moving to a new, more detailed, file format that will differentiate the tests in reporting so that CDC can display the viral test data and serologic test data separately on the CDC COVID Data Tracker.[23]

i. Testing for an Active COVID-19 Infection

Widespread viral detection testing for COVID-19 allows for rapid detection of COVID-19 cases in the U.S. The FDA has therefore issued, and revised, guidance for laboratories and commercial manufacturers to help accelerate the use of tests that are developed.[24]

The FDA has defined COVID-19 molecular tests as tests that detect COVID-19 nucleic acids from human specimens.[25] Molecular tests, also referred to as nucleic acid amplification

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[19] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Protect Yourself* (last reviewed on Apr. 24, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.
[20] U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: Daily Roundup May 27, 2020* (May 27, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-may-27-2020.
[21] U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (May 2020), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.
[22] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Testing Data in the US* (last visited May 29, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html.
[23] *Id*.
[24] *See* U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (May 2020), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.
[25] U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (May 2020), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.

tests or PCR tests, indicate if a patient is actively infected with COVID-19.[26] The tests detect the presence of characteristic sequences of COVID-19 genetic material (RNA) in respiratory samples of patients. If the viral RNA is detected, it suggests COVID-19 is likely present.[27] Nucleic acid amplification testing requires respiratory samples from the patient since COVID-19 is a respiratory virus.[28] Nasopharyngeal swabs are commonly used to collect the sample for this type of testing, but the FDA has expanded the types of swabs that can be used to collect a sample and also approved a test that utilizes a saliva sample, which does not require a swab.[29] There are two types of these diagnostic tests: laboratory-based and rapid point-of-care tests.

Antigen tests look for antigens that the virus produces, which show its presence in blood and saliva. Antigen tests are less precise than PCR tests, but they enable fast and widespread testing. Moreover, the advantage of antigen testing over PCR tests is that it can show whether the virus is intact and still viable, and thus whether the patient is infectious. Dr. Deborah Birx, the White House Task Force Coordinator, has described antigen testing as a significant testing "breakthrough."[30] FDA recently granted an EUA to the first antigen test for COVID-19.[31]

ii. Testing for a Previous COVID-19 Infection

Antibody tests, also commonly referred to as serology tests, are simple blood tests that can detect whether a person has developed antibodies to the COVID-19 virus.[32] A person develops antibodies to a virus when a person is exposed to the virus and their immune system launches an antibody-forming immune response.[33]

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[26] American Society for Microbiology, *COVID-19 Testing FAQs* (Apr. 29, 2020), *available at* https://www.asm.org/Articles/2020/April/COVID-19-Testing-FAQs.
[27] Amy Maxmen, *Thousands of coronavirus tests are going unused in US labs*, NATURE (Apr. 9, 2020), *available at* https://www.nature.com/articles/d41586-020-01068-3.
[28] American Society for Microbiology, *COVID-19 Testing FAQs* (Apr. 29, 2020), *available at* https://asm.org/Articles/2020/April/COVID-19-Testing-FAQs.
[29] On April 10, 2020, the FDA issued an EUA to Rutgers Clinical Genomics Laboratory-Rutgers University for a COVID-19 high complexity molecular-based laboratory developed test that uses saliva as the primary test biomaterial, or sample, for the COVID-19 virus. Rutgers, *New Rutgers Saliva Test for Coronavirus Gets FDA Approval* (Apr. 13, 2020), *available at* https://www.rutgers.edu/news/new-rutgers-saliva-test-coronavirus-gets-fda-approval; U.S. Food and Drug Administration, *Emergency Use Authorizations* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.
[30] NBC News, *Birx: U.S. needs "breakthrough" on antigen testing to aid in reopening* (Apr. 27, 2020), *available at* https://www.nbcnews.com/politics/meet-the-press/birx-u-s-needs-breakthrough-antigen-testing-aid-re-opening-n1192901.
[31] On May 8, 2020, Quidel announced that the company had received an EUA from the FDA to market a rapid antigen COVID-19 diagnostic assay. Thomas M. Burton, *FDA Grants Emergency-Use Status for First Coronavirus Antigen Test*, THE WALL STREET JOURNAL (May 9, 2020), *available at* https://www.wsj.com/articles/fda-to-grant-emergency-use-status-for-first-coronavirus-antigen-test-by-quidel-corp-11589031815.
[32] Cynthia Demarco, *7 things to know about COVID-19*, MD Anderson Cancer Center (Apr. 22, 2020), *available at* https://www.mdanderson.org/publications/cancerwise/7-things-to-know-about-coronavirus-COVID19-antibody-testing.h00-159381156.html.
[33] *Id*.

Antibody tests must be differentiated from diagnostic tests that identify active infections and should not be used as the sole basis to diagnose an active infection for COVID-19.[34] Rather than detecting the virus itself, antibody tests detect the body's immune response to the infection caused by COVID-19.[35] According to the CDC, it may take an individual one to three weeks after infection to develop antibodies.[36] Currently, a positive antibody test only confirms that a person has or has had a COVID-19 infection.[37] We do not yet know whether a positive COVID-19 antibody test result also means that a person has full or partial immunity to COVID-19.[38] Researchers are currently trying to determine the appropriate use of antibody tests, whether someone who is antibody positive is resistant to reinfection, and if so, how long that person is resistant to reinfection.[39]

b. Testing Capacity

There have been significant obstacles to date in creating a unified and robust testing capacity in the U.S., including limited access to necessary supplies and not fully utilizing all available testing capacity. Given these challenges, the U.S. has focused a significant amount of effort on increasing testing capacity.

In a recent report to Congress, titled the "COVID-19 Strategic Testing Plan," the Trump Administration highlighted the enhanced testing capacity over the last few months. For example, in early March, only a few thousand COVID-19 tests were performed each day.[40] By mid-May, about 300,000 COVID-19 tests were performed each day, with the number of tests performed increasing by 25 to 30 percent per week.[41] According to the plan, the U.S. will be able to perform at least 40 to 50 million tests per month by September.[42] There have been over 12 million nucleic acid tests performed in the U.S. with more than 2 million completed each week recently.[43]

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[34] U.S. Food and Drug Administration, *EUA Authorized Serology Test Performance* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance.
[35] *Id*.
[36] Centers for Disease Control and Prevention, *Testing for COVID-19* (May 1, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html.
[37] National Cancer Institute, *NCI Part of Federal Effort to Evaluate Antibody Tests for Novel Coronavirus* (May 5, 2020), *available at* https://www.cancer.gov/news-events/cancer-currents-blog/2020/covid-19-nci-antibody-testing-review.
[38] Cynthia Demarco, *7 things to know about COVID-19*, MD Anderson Cancer Center (Apr. 22, 2020), *available at* https://www.mdanderson.org/publications/cancerwise/7-things-to-know-about-coronavirus-COVID19-antibody-testing.h00-159381156.html.
[39] U.S. Food and Drug Administration, *EUA Authorized Serology Test Performance* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance; Centers for Disease Control and Prevention, *Serology Testing* (May 5, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html.
[40] U.S. Dep't of Health and Human Services, *Report to Congress, COVID-19 Strategic Testing Plan*, at 10 (May 24, 2020).
[41] *Id*.
[42] *Id*. at 19.
[43] *Id*. at 13.

It has been reported that available capacity at commercial and academic laboratories in the U.S. is not being fully utilized due to a shortage of testing component supplies and low order volumes because people who are mildly symptomatic are instructed to stay home and not seek testing, among other factors.[44] The federal government has taken a number of actions to address supply chain issues. For example, through the Laboratory Diagnostic Testing Task Force, the federal government has closely coordinated with commercial manufacturers and laboratories to develop a better understanding of challenges in the supply chain and expected inventory.[45] Moreover, HHS and the Federal Emergency Management Agency (FEMA) have procured swabs and viral transport media that they have provided to states in support of state testing plans.[46]

The Trump Administration has entered into public-private partnerships with stakeholders to increase testing capacity. For example, the Administration worked with private industry to establish a drive-through testing program that continues to expand with the use of provider-administered swab tests at various retail locations. As of May 16, 2020, there were over 2,155 drive-through testing sites nationwide.[47] Similarly, the White House Task Force established the Community-Based Testing Sites (CBTS) program to expand critical testing capacity for symptomatic and asymptomatic individuals, while sharing best practices for testing sample collection and preserving personal protective equipment (PPE).[48]

Additional examples of the steps the federal government has taken to increase testing capacity and testing supplies in the U.S. are discussed in Section V of this memorandum.

c. Testing Strategies

States, working with the federal government, should determine a strategy that utilizes all available testing resources, including rapid point-of-care diagnostic testing, high-throughput laboratory testing, and antibody testing. States should implement and maintain these strategies going into the fall. An effective testing strategy should address the necessary frequency of testing, risk levels for different populations, identifying asymptomatic and mild cases through surveillance, and contact tracing, among other issues. The federal government currently recommends that all states try to test a minimum of two percent of their population in May and June 2020.[49]

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[44] Brianna Abbott and Sarah Krouse, *Coronavirus Testing Capacity is Going Unused*, THE WALL STREET JOURNAL (Apr. 29, 2020), *available at* https://www.wsj.com/articles/coronavirus-testing-capacity-is-going-unused-11588152602.
[45] U.S. Dep't of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan, at 28 (May 24, 2020).
[46] *Id*. at 28.
[47] Mui, Katie, *Where Can I Get a Drive-Thru Coronavirus (COVID-19) Test Near Me?*, GOODRX (May 8, 2020), *available at* https://www.goodrx.com/blog/drive-thru-coronavirus-testing-near-me/.
[48] Claire Duffy, *Bill Gates explains how the United States can safely ease coronavirus restrictions,* CNN BUSINESS (Apr. 26, 2020), *available at* https://www.stltoday.com/business/bill-gates-explains-how-the-united-states-can-safely-ease-coronavirus-restrictions/article_ed0e7d45-e049-597c-a4eb-ca8687a674ff.html.
[49] U.S. Department of Health and Human Services, *Report to Congress, COVID-19 Strategic Testing Plan*, at 17 (May 24, 2020).

An effective testing strategy in one state may not be effective in another state. Similarly, a strategy for one region of a state may not be effective in other regions within the state. Testing strategies should address regional variances where appropriate.

d. Testing for COVID-19 and Influenza in the Fall

A second wave of COVID-19 cases could occur at the same time as influenza season in the fall. The development of combined diagnostic testing kits for both COVID-19 and influenza would allow providers quickly to determine whether a patient is infected with influenza or COVID-19. In particular, by providing point-of-care testing at hospitals for symptomatic cases, COVID-19 and influenza cases can be differentiated and separated to prevent co-infections and improve surveillance of the two viruses. The FDA has already issued two EUAs for laboratory diagnostic tests that detect numerous respiratory viruses, including both COVID-19 and influenza.[50]

IV. SURVEILLANCE

a. U.S. Surveillance Systems for COVID-19

According to the CDC, "[p]ublic health surveillance is the ongoing, systematic collection, analysis, and interpretation of health related data essential to planning, implementation, and evaluation of public health practice."[51] The U.S.' COVID-19 surveillance goals are to: (1) monitor the spread and intensity of COVID-19 disease in the U.S.; (2) understand disease severity and the spectrum of illness; (3) understand risk factors for severe disease and transmission; (4) monitor for changes in the virus that causes COVID-19; (5) estimate disease burden; and (6) produce data for forecasting COVID-19 spread and impact.[52]

While the U.S. does not currently have a unified, comprehensive, and designated national surveillance system specific to COVID-19, CDC is using multiple surveillance systems run in collaboration with state, local, and territorial health departments, public health, commercial and clinical laboratories, vital statistics offices, health care providers, emergency departments, and academic partners to monitor COVID-19 in the U.S.[53] CDC's surveillance program for COVID-19 "is built on a combination of existing influenza and viral respiratory diseases surveillance systems, syndromic surveillance systems, case reporting systems, proactive monitoring for

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[50] U.S. Food and Drug Administration, *Emergency Use Authorizations* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd; Biomerieux, *BIOFIRE Respiratory Panel 2.1 (RP2.1) with SARS-CoV-2 obtains FDA Emergency Use Authorization* (May 4, 2020), *available at* https://www.biomerieux.com/en/biofirer-respiratory-panel-21-rp21-sars-cov-2-obtains-fda-emergency-use-authorization.

[51] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), FAQ Data & Surveillance* (last updated Apr. 17, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/faq-surveillance.html.

[52] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), COVIDView, Purpose and Method* (last updated Apr. 17, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/purpose-methods.html.

[53] *Id*.

asymptomatic cases in areas of demonstrated vulnerabilities, commercial laboratory reporting, ongoing research platforms employed for the COVID-19 response, and new systems."[54] The CDC uses multiple systems and epidemiology networks that "use laboratory submitted specimens, electronically transmitted data, and other sources to generate an ongoing picture of disease spread, intensity, and severity, and produce data to address the key questions for directing and refining the US response."[55]

On April 3, 2020, the CDC launched a website—COVIDView—which "provides a weekly surveillance summary and interpretation of a variety of surveillance systems that will be used to track the progression and severity of COVID-19 disease throughout the course of the pandemic" in the U.S.[56] The data summarized in COVIDView comes "from a combination of existing influenza and viral respiratory disease surveillance systems, syndromic surveillance systems, and reporting laboratory results," which together "create an ongoing picture of the spread of SARS-CoV-2 and its effects in the United States and provides data to inform the U.S. national public health response to COVID-19."[57] In addition, CDC's COVID Data Tracker contains the total number of COVID-19 cases and deaths in the U.S., as well as breakdowns by state, reported to CDC by state and territorial jurisdictions since January 21 2020, with the exception of those who were repatriated to the U.S. from Wuhan, China, and Japan.[58] In addition to tracking the number of cases, the CDC COVID Data Tracker has a page specifically devoted to U.S. testing figures, including national and state data, which is reported by U.S. laboratories, including commercial and reference labs, public health laboratories (PHLs), and hospital laboratories.[59]

b. Enhancing the U.S. Surveillance System for COVID-19

Congress has previously provided funding to improve public health surveillance, including for a multi-year effort to support modernization of public health data surveillance and analytics. In addition, Congress has taken recent action to enhance surveillance systems.

For example, the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, which was signed into law on March 6, 2020, provided not less than $950 million for grants to or cooperative agreements with states, localities, territories, tribes, tribal organizations, urban Indian health organizations, and health service providers to tribes to carry out surveillance,

[54] Centers for Disease Control and Prevention, *CDC Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America Up Again* (May 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/CDC-Activities-Initiatives-for-COVID-19-Response.pdf.
[55] *Id*.
[56] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Purpose & Methods, COVIDView* (last updated Apr. 17, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/purpose-methods.html.
[57] *Id*.
[58] Centers for Disease Control and Prevention, *CDC COVID Data Tracker* (last visited May 28, 2020), *available at* https://www.cdc.gov/covid-data-tracker/.
[59] *Id*.

epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities.[60]

In addition, the Coronavirus, Aid, Relief, and Economic Security Act (CARES Act), which was signed into law on March 27, 2020, provided not less than $500 million for public health data surveillance and analytics infrastructure modernization and not less than $1.5 billion for grants to or cooperative agreements with states, localities, territories, tribes, tribal organizations, urban Indian health organizations, and health service providers to tribes to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities.[61] Further, the Act requires any laboratory that performs tests to detect COVID-19 to report the results, both positive and negative, to the Secretary of HHS during the period of the public health emergency.[62]

In addition, the Paycheck Protection Program and Health Care Enhancement Act, which was signed into law on April 24, 2020, provided an additional $25 billion to the Public Health and Social Services Emergency Fund for necessary expenses to research, develop, validate, manufacture, purchase, administer, and expand capacity for COVID-19 tests to monitor and suppress COVID-19, including, among other things, to conduct surveillance and contact tracing.[63]

V. FEDERAL RESPONSE

a. Congress

Congress has passed legislation in response to the COVID-19 pandemic, including historic levels of funding. Recent actions taken by Congress include the following:

- On March 5, 2020, Congress passed the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, and on March 6, 2020, President Trump signed the bill into law.[64] The Act provided $8.3 billion in emergency funding for domestic and global efforts in responding to the COVID-19 outbreak. Of the $8.3 billion, $6.7 billion was designated for the domestic response and $1.6 billion was designated for the international response.[65] Of the $6.7 billion that was designated for the U.S. response, $6.2 billion was for HHS, including $3.4 billion for the Office of the Secretary – Public

[60] Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. 116-123 (2020).
[61] Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. 116-136 (2020).
[62] *Id*.
[63] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).
[64] Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. 116-123 (2020).
[65] Stephanie Oum, Adam Wexler, and Jennifer Kates, *The U.S. Response to Coronavirus: Summary of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*, KAISER FAMILY FOUNDATION (Mar. 11, 2020), *available at* https://www.kff.org/global-health-policy/issue-brief/the-u-s-response-to-coronavirus-summary-of-the-coronavirus-preparedness-and-response-supplemental-appropriations-act-2020/.

Health and Social Services Emergency Fund; $1.9 billion for the CDC; $836 million for the National Institute of Allergy and Infectious Diseases; and $61 million for the FDA.[66]

- On March 18, 2020, Congress passed, and President Trump subsequently signed into law, the Families First Coronavirus Response Act.[67] The Act provided more than $2.5 billion in additional emergency relief for domestic efforts in responding to the COVID-19 outbreak by providing paid sick leave and free coronavirus testing, expanding food assistance and unemployment benefits, and requiring employers to provide additional protections for health care workers.

- On March 27, 2020, Congress passed, and President Trump subsequently signed into law, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act.[68] The CARES Act provided an additional $2.3 trillion in emergency funding relief for domestic and global efforts to address the COVID-19 pandemic, and contains a number of health-related provisions, including insurance coverage of COVID-19 testing. In addition, of the $2.3 trillion, the Act provided for $4.3 billion to CDC, including $300 million to be transferred to the Infectious Diseases Rapid Response Reserve Fund; not less than $500 million for global disease detection and emergency response; and not less than $1.5 billion for grants to or cooperative agreements with states, localities, territories, tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities.[69]

- On April 23, 2020, Congress passed, and President Trump subsequently signed into law, the Paycheck Protection Program and Health Care Enhancement Act.[70] The Act provided an additional $484 billion in funding relief to address the COVID-19 pandemic, including health related provisions and additional funding for the Paycheck Protection Program.[71] Among other things, the Act provided an additional $25 billion to the Public Health and Social Services Emergency Fund for necessary expenses to research, develop, validate, manufacture, purchase, administer, and expand capacity for COVID-19 tests to effectively monitor and suppress COVID-19, including, among other things, to conduct surveillance and contact tracing.[72] Of the $25 billion, the Act provided not less than $11 billion to states, localities, territories, and tribes to develop, purchase, administer, process, and analyze COVID-19 tests, scale-up laboratory capacity, trace contacts, and support employer testing, and required states and territories receiving funding to submit to the Secretary of HHS, its plan for COVID-19 testing, including goals for the remainder of

[66] *Id*.
[67] Families First Coronavirus Response Act, Pub. L. 116-127 (2020).
[68] Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. 116-136 (2020).
[69] *Id*.
[70] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).
[71] Kellie Moss, *The Paycheck Protection Program and Health Care Enhancement Act: Summary of Key Health Provisions*, KAISER FAMILY FOUNDATION (May 1, 2020), *available at* https://www.kff.org/coronavirus-covid-19/issue-brief/the-paycheck-protection-program-and-health-care-enhancement-act-summary-of-key-health-provisions/.
[72] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).

calendar year 2020.[73] The state testing plans are required to be submitted no later than 30 days after April 24, 2020, when the Act became law.[74] In addition, the Act provided no less than $1 billion to CDC, and up to $1 billion to cover the cost of testing for the uninsured, among other provisions.[75]

In addition to these major pieces of legislation, Congress continues to monitor the nation's response to the COVID-19 pandemic to evaluate whether additional legislation is needed. In addition to monitoring whether additional resources are needed, Congress will continue to conduct oversight over the COVID-19 response, including new authorities provided and funding appropriated to address COVID-19 within the U.S.

b. Executive Branch

Since early January, the Executive Branch has taken action to prepare for, and respond to, the COVID-19 pandemic, even before the first patient with confirmed COVID-19 was identified in the U.S. For example, on January 7, 2020, CDC established a COVID-19 Incident Management System, and on January 21, 2020, CDC activated its Emergency Operations Center to improve the provision of ongoing support to the COVID-19 response. On January 31, 2020, HHS Secretary Alex M. Azar II declared a public health emergency for the U.S. In addition, on February 25, 2020, President Trump announced that Vice President Pence would lead the Administration's response to COVID-19. On March 13, 2020, President Trump declared a national emergency as a result of the COVID-19 pandemic.

i. Efforts to Increase Testing Capacity in the U.S.

On January 10, 2020, China researchers posted the sequencing of COVID-19 and two weeks later, on January 24, 2020, CDC publicly posted the assay protocol for the reverse transcription polymerase chain reaction (RT-PCR) test. On February 3, 2020, CDC submitted an EUA package to the FDA to expedite FDA's permitted use of the CDC diagnostic panel in the U.S. On February 4, 2020, FDA issued the EUA for the CDC diagnostic panel and distribution of the test kits began the following day. CDC began shipping the sharable viral stocks to the BEI biorepository on February 4, 2020, to enable broad sharing with appropriate entities. On February 8, 2020, CDC was made aware of performance issues with respect to one of the three reagents, which led to some laboratories not being able to verify the test performance. CDC and FDA investigated the problem, and the agencies determined a solution to remanufacture the reagents and distribute new test kits. On February 27, 2020, CDC began distributing new tests kits and the next day approximately 40 PHLs in the U.S. were able to perform the diagnostic test.

[73] *Id*.
[74] *Id*.
[75] Kellie Moss, *The Paycheck Protection Program and Health Care Enhancement Act: Summary of Key Health Provisions*, KAISER FAMILY FOUNDATION (May 1, 2020), *available at* https://www.kff.org/coronavirus-covid-19/issue-brief/the-paycheck-protection-program-and-health-care-enhancement-act-summary-of-key-health-provisions/.

On February 29, 2020, FDA issued guidance to provide a policy for certain laboratories—laboratories certified to perform high-complexity testing under the Clinical Laboratory Improvement Amendments (CLIA)—seeking to develop diagnostic tests for COVID-19 in order to achieve more rapid testing capacity.[76] On March 16, 2020, FDA announced updated guidance allowing states to take responsibility for tests developed and used by laboratories in their states.[77] According to this policy, states can set up a system in which they take responsibility for authorizing such tests, and the laboratories will not engage directly with the FDA.[78] In addition, the March 16 guidance expanded the February 29 guidance to include commercial manufacturers distributing and labs using new commercially developed tests in addition to CLIA laboratories.

ii. Efforts to Increase Testing Supplies in the U.S.

As the number of COVID-19 tests and testing capacity ramped up across the nation, the U.S. began to see supply shortages for various components needed to collect samples and perform the tests, including swabs, transport media, reagents, and PPE for individuals collecting and testing samples. Due to a shortage of supplies needed to administer COVID-19 diagnostic tests, on March 19, 2020, HHS and the U.S. Department of Defense coordinated an emergency international airlift of 500,000 swabs and sample kits used in the COVID-19 testing process in an effort to increase diagnostic testing in the U.S. In addition, on March 23, 2020, FDA approved self-collected samples for testing, which was done to reduce the strain on medical supplies and professionals. This approval allowed for foam swabs swabbed shallowly in the nose to be used in lieu of nasopharyngeal swabs. Further, FDA provided updated guidance on March 24, 2020, regarding the use of swabs, including the types of swabs that providers can use for COVID-19 tests.[79]

On March 29, 2020, President Trump announced that FEMA is working with the private sector to launch Project Airbridge to expedite the movement of critical supplies from other countries to the U.S., including respirators, gloves, surgical masks, surgical gowns, thermometers, face shields, coveralls, stethoscopes, oxygen masks, and cannulas. While these supplies are largely used by health care workers caring for and treating patients, some of these supplies, particularly the PPE, are also used by those administering and performing COVID-19 tests. As of May 26, 2020, Project Airbridge has completed 173 flights with an additional 53

[76] U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics* (Feb. 29, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics.
[77] U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics* (Mar. 16, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help.
[78] *Id*.
[79] U.S. Food and Drug Administration, *FAQs on Testing for SARS-CoV-2* (last visited May 28, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#troubleobtainingviraltransport.

scheduled, or in transit, for a total of approximately 226 flights.[80] Project Airbridge is one example of efforts by the federal government's Supply Chain Stabilization Task Force, which was created "to address limited supply of critical protective and life-saving equipment."[81]

To support the Administration's Testing Blueprint and state goals for testing, FEMA is also working to source and procure testing materials, specifically testing swabs and transport media. As of May 28, FEMA has procured and delivered 9.9 million swabs and 5.5 million units of media so far in the month of May.[82]

VI. STATE RESPONSES

a. State Responses to the COVID-19 Pandemic

Every state and the District of Columbia has had to respond rapidly to the COVID-19 pandemic, and the pandemic has impacted each jurisdiction in different ways. The federal government has worked with states in their individual responses to the COVID-19 pandemic, including providing funding through the legislation discussed in Section V of this memorandum.

i. Colorado

As of May 27, 2020, Colorado reported 24,503 cases and 1,350 deaths due to COVID-19 to the CDC.[83] Colorado reported having performed 107,696 tests with a percent positive range of 11 to 20 percent.[84]

Colorado has taken action to address the COVID-19 pandemic, and many of these actions are detailed on the Governor's website and the Colorado Official State Web Portal.[85] Some examples of these actions include: (1) Governor Polis expanding testing capacity, and on May 18, 2020, announcing that "Colorado has reached a critical goal, and now has the supplies and capacity to test anyone with COVID-19 symptoms;"[86] (2) Governor Polis establishing a COVID Health Response Team on April 27, 2020, to address racial inequities in positive COVID-19

[80] FEMA Advisory: COVID-19 Daily Briefing Points (May 27, 2020) (on file with the Committee).
[81] FEMA, *Coronavirus (COVID-19) Pandemic: Supply Chain Stabilization Task Force* (Mar. 30, 2020), *available at* https://www.fema.gov/fema-supply-chain-stabilization-task-force.
[82] FEMA Advisory: COVID-19 Daily Briefing Points (May 28, 2020) (on file with Committee).
[83] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19)* (last visited May 27, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.
[84] Centers for Disease Control and Prevention, *U.S. COVID Testing* (last visited May 27, 2020), *available at* https://www.cdc.gov/covid-data-tracker/.
[85] Colorado Governor Jared Polis, *Press Releases* (May 26, 2020), *available at* https://www.colorado.gov/governor/news; Colorado Official State Web Portal, *Press Releases* (last visited May 28, 2020), *available at* https://covid19.colorado.gov/news-0.
[86] Colorado Governor Polis, *Gov. Polis Announces Expanded Testing Capacity, Including All Who are Symptomatic* (May 18, 2020), *available at* https://www.colorado.gov/governor/news/gov-polis-announces-expanded-testing-capacity-including-all-who-are-symptomatic.

cases and deaths;[87] and (3) Governor Polis announcing on April 17, 2020, that the State was deploying the Colorado National Guard to assist with testing efforts in nursing homes.[88]

ii. Michigan

As of May 27, 2020, Michigan reported 55,104 cases and 5,266 deaths due to COVID-19 to the CDC.[89] Michigan reported having performed 494,605 tests with a percent positive range of 11 to 20 percent.[90]

Michigan has taken action to address the COVID-19 pandemic, and many of these actions are detailed on the Governor's website and the Michigan Department of Health and Human Service's website.[91] Some examples of these actions include: (1) Governor Whitmer signing an Executive Order on May 26, 2020, expanding the types of medical personnel that can order a test, creating a new category of community testing sites that offer testing to anyone with reason to be tested without an advance order and without charging an out-of-pocket cost;[92] and (2) Governor Whitmer announcing a process to chart process for safe and equitable reopening of schools on May 15, 2020.[93]

iii. Arkansas

As of May 27, 2020, Arkansas reported 6,180 cases and 119 deaths due to COVID-19 to the CDC.[94] Arkansas reported having performed 96,258 tests with a percent positive range of 0 to 5 percent.[95]

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[87] Colorado Governor Polis, *Gov. Polis Updates Coloradans on State Response to COVID-19* (Apr. 17, 2020), *available at* https://www.colorado.gov/governor/news/gov-polis-updates-coloradans-state-response-covid-19.
[88] *Id*.
[89] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19)* (last visited May 27, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.
[90] Centers for Disease Control and Prevention, *U.S. COVID Testing* (last visited May 27, 2020), *available at* https://www.cdc.gov/covid-data-tracker/.
[91] The Office of Governor Gretchen Whitmer, *Press Releases* (last visited May 27, 2020), *available at* https://www.michigan.gov/whitmer/0,9309,7-387-90499_90640---,00.html; Michigan Department of Health and Human Services, *Coronavirus Disease 2019 (COVID-19)* (last visited May 28, 2020), *available at* https://www.michigan.gov/mdhhs/.
[92] The Office of Governor Gretchen Whitmer, *Governor Whitmer Signs Executive Order Expanding COVID-19 Testing Sites* (May 26, 2020), *available at* https://www.michigan.gov/whitmer/0,9309,7-387-90499-530120--,00.html.
[93] The Office of Governor Gretchen Whitmer, *Governor Whitmer Announces Process to Chart Path for the Safe and Equitable Reopening of Schools* (May 15, 2020), *available at* https://www.michigan.gov/whitmer/0,9309,7-387-90499_90640-529397--,00.html.
[94] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19)* (last visited May 27, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.
[95] Centers for Disease Control and Prevention, *U.S. COVID Testing* (last visited May 27, 2020), *available at* https://www.cdc.gov/covid-data-tracker/.

Arkansas has taken action to address the COVID-19 pandemic, and many of these actions are detailed on the Governor's website and the Arkansas Department of Health's website.[96] Some examples of these actions include: (1) Governor Hutchinson creating a Testing Advisory Group on April 21, 2020, to expand and increase testing in the State;[97] (2) Governor Hutchinson announcing a partnership with Community Health Centers across the State and Walmart to support testing initiatives;[98] and (3) Governor Hutchinson announcing on May 19, 2020, that all nursing home staff and residents will be tested for COVID-19 beginning June 1, 2020.[99]

b. State-Specific Testing Plans

The Paycheck Protection Program and Health Care Enhancement Act requires that each state or jurisdiction that receives funding for testing submit a testing plan to HHS. Plans for May and June must be submitted by May 30, 2020, and plans for the remainder of the year must be submitted by June 15, 2020.[100]

The federal government recommends that all states try to test two percent of their population in May and June 2020, and the federal government has provided technical assistance to each state to help maximize laboratory instrument capacity and establish initial testing goals for May and June.[101] According to the "COVID-19 Strategic Testing Plan," Colorado's testing target for May is about 3.4 percent of the State's population, Michigan's testing target for May is about 4.5 percent of the State's population, and Arkansas' testing target for May is about 3 percent of the State's population.

[96] Arkansas Governor Asa Hutchinson, *COVID-19 Information* (last visited May 28, 2020), *available at* https://govstatus.egov.com/ar-covid-19?_ga=2.196696937.495569030.1590636980-2056438593.1590155179; Arkansas Department of Health, *Press Releases* (last visited May 28, 2020), *available at* https://www.healthy.arkansas.gov/news.
[97] Arkansas Governor Asa Hutchinson, *Governor Hutchinson's Weekly Address: Testing: A Critical Part of Fighting the Virus* (May 15, 2020), *available at* https://governor.arkansas.gov/news-media/press-releases/governor-hutchinsons-weekly-address-testing-a-critical-part-of-fighting-the.
[98] *Id*.
[99] *Coronavirus in Ark.: Gov. Hutchinson announces goal to test every nursing home resident, staff starting June 1*, FOX 16 NEWS (May 19, 2020), *available at* https://www.fox16.com/news/coronavirus-in-arkansas-governor-asa-hutchinson-to-give-update-on-states-response-at-130-p-m-3/.
[100] U.S. Department of Health and Human Services, *Report to Congress, COVID-19 Strategic Testing Plan*, at 15 (May 24, 2020).
[101] *Id*.